UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* LAURIE SIMPSON, *Plaintiff*,	Honorable Jose L. Linares United States District Judge
v.	
BAYER CORPORATION; BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER HEALTHCARE LLC; and BAYER AG, *Defendants*.	Civ. No. 05-3895

DEFENDANTS' RESPONSE TO THE UNITED STATES' STATEMENT OF INTEREST AS TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

None of the arguments in the Government's Statement of Interest saves Simpson's complaint from dismissal. The Statement takes no position with respect to the majority of legal issues presented in this case, including Simpson's sweeping theory that every claim submitted for Trasylol was "false" because the drug was supposedly "misbranded" and her failure to plead specific factual allegations sufficient to survive a motion to dismiss under Federal Rules of Civil Procedure 8, 9(b), 12(b)(1), and 12(b)(6). Rather, the Government's narrow Statement is submitted solely for the purpose of "clarifying the United States' position" on three "issues of unique concern with respect to the interpretation and application of federal law." Letter dated June 18, 2013, from Assistant United States Attorney David E. Dauenheimer to Hon. Jose L. Linares [DE 117].

I. THE GOVERNMENT'S STATEMENT DOES NOT SALVAGE SIMPSON'S FCA COUNTS.

The Government devotes most of the Statement to explaining several ways in which the "promotion of prescription drugs for non-covered uses or violations of the AKS" ("Anti-Kickback Statute") could theoretically give rise to actionable claims under the FCA." Statement at 2 (capitalization altered). But the Statement does not dispute Bayer's fundamental argument that Simpson has not properly alleged facts sufficient to support liability.

Indeed, the Statement *agrees* with Bayer that "not every violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. § 301 *et seq.*, or FDA regulations is a *per se* violation of the FCA" and that a drug law violation cannot support FCA liability unless it "has a nexus to payment." *Id.* And, the Statement identifies only one specific way in which a relator may allege "a nexus to payment" — by alleging that the claim "seeks payment for treatment that is not statutorily eligible for reimbursement." *Id.* at 2-3. This, too, is consistent with Bayer's argument. *See* Reply Brief in Support of Defendants' Motion to Dismiss ("Reply") at 23 ("If compliance with the legal requirement is not a condition for payment, then the alleged violation is not material [to the government's payment decision]."); *accord United States ex rel. Wilkins v. United Health Care Group,* 659 F.3d 295, 305 (3d Cir. 2011).[1]

[1] The Government notes that an FCA complaint need not allege that regulators would have withdrawn approval for the drug but for the alleged fraud, provided the complaint alleges that the defendant "knowingly caused the submission of … non-reimbursable prescription claims." Statement at 3 n.1. The Government appears to be conflating separate theories of liability. To the extent Simpson is trying to advance a theory that Bayer's fraud prevented the FDA from taking action, *see, e.g.*, Opposition to Defendant's Motion to Dismiss ("Opp.") at 21-22, she cannot adequately plead materiality without alleging with particularity what FDA would have done absent the fraud—assuming *arguendo* that a private relator could ever proceed on such a theory. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001) (holding private fraud-on-FDA actions interfere with FDA's exercise of its regulatory authority).

Moreover, the Statement's delineation of the manner in which a relator may allege a "nexus to payment" is narrow and, it is critical to note, largely inapplicable to the allegations in Simpson's complaint. The Government makes no attempt to support Simpson's sweeping theory that such a nexus exists because Bayer's alleged off-label promotion purportedly rendered the drug "misbranded" and therefore "illegal in interstate commerce." *See* Opp. at 19; *compare* Reply at 24-27 (discussing flaws with theory). Instead, the Statement addresses only two ways in which a drug law violation could make a claim "not statutorily eligible for reimbursement": (1) by leading to the submission of Medicare or Medicaid claims for off-label uses that are not covered by the program (generally, a treatment that is not medically reasonable and necessary), Statement at 3; or (2) by leading to the presentment or payment of a claim that is "tainted by" an AKS violation, *id.* at 5.

Neither of these theories provides a basis for Simpson to proceed with her FCA counts. Most of Simpson's counts are not based upon these theories, and those that are, are not supported by allegations sufficient to state a claim.

A. Simpson Has Not Properly Alleged That Any Claim Was Statutorily Ineligible for Payment Under Medicare or Medicaid.

The Government' first theory — that a claim can be false if a drug law violation leads to the submission of Medicare or Medicaid claims that are statutorily ineligible for payment, Statement at 3-5 — does not save any of Simpson's FCA counts. Counts 1 and 2 allege FCA violations related to programs

other than Medicare and Medicaid, and thus find no support in the Statement. Counts 3-6, which allege FCA violations for Medicaid and Medicare claims, fail because they are not based on any violated payment condition, but rest instead on Simpson's claim that all sales of Trasylol were "illegal"—a theory the Government does not support or defend. *See* Seventh Am. Compl. ("Compl.") ¶¶ 298-53; Opp. at 18-22; Reply at 23-25.

The only counts that rest upon a theory discussed in the Statement are Counts 7 and 8, which allege that Bayer's supposed off-label marketing of Trasylol led to the submission of Medicare claims that were not reimbursable because they were for uses that were not "reasonable and necessary" under 42 U.S.C. § 1395y(a)(1)(A). *See* Statement at 3-5; Compl. at ¶¶ 354-65. But Simpson has not identified any uses of Trasylol that were not "reasonable and necessary." As Bayer previously demonstrated, courts and government reimbursement programs generally consider off-label uses to be medically accepted and thus "reasonable and necessary" if they are supported by a listing in a major drug compendium, and each of the off-label uses at issue here was supported by a listing in a major drug compendium. *See* Memorandum of Law in Support of Defendants' Motion to Dismiss ("Bayer Mem.") at 25 & nn.18-19, Exs. K, L. The Government does not

dispute this fact, and takes no position on whether the uses of Trasylol at issue were "reasonable and necessary."[2]

Rather, the Government contends that "the determination of what is reasonable and necessary for purposes of Medicare coverage is committed to the discretion of the Secretary of the Department of Health and Human Services." Statement at 4-5.[3] Simpson has not alleged that the Secretary exercised this

[2] Unremarkably, the Government notes that an *adverse* listing in a compendium may not demonstrate that a given off-label use is medically accepted. Statement at 3 & n.2. But the Government has not disputed that there is a *supportive* compendium listing for each off-label use at issue here, nor has Simpson countered Bayer's showing. *See* Bayer Mem. at 25 n.19 & Exs. K, L; Reply at 26.

[3] The Government therefore submits that "the determination of what is reasonable and necessary for purposes of Medicare coverage" does not depend upon a physician's judgment. Statement at 4. However, the Medicare statute provides that compliance with the "reasonable and necessary" requirement is not a basis for the government to withhold payment if the patient and provider "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services." 42 U.S.C. §1395pp(a)(2). The Government does not discuss this exception, upon which Bayer explicitly relied. *Compare* Bayer Mem. at 25 (citing § 1395pp(a)), *with* Statement at 4-5 (asserting Bayer made its argument on this point "without any supporting authority"). Moreover, the cases cited by the Government expressly rely on the exception. *See Int'l Rehabilitative Scis., Inc. v. Sebelius*, 688 F.3d 994, 997-98 (9th Cir. 2012) (when § 1395pp(a) applies, Medicare payment is required "[e]ven if a coverage claim is denied on the ground that the items or services were not 'reasonable or necessary'"); *Svidler v. Dept. of Health and Human Servs.*, No. C 03-3593 MJJ, 2004 WL 2005781, at *1 (N.D. Cal. Sept. 8, 2004) ("Medicare provides that reimbursement may be made for services that are determined not to be covered under 42 U.S.C. §§ 1395y(a)(1) if both the beneficiary and the provider" lacked the requisite knowledge under § 1395pp(a)). Because Simpson's complaint lacks any allegations regarding provider knowledge, she has not properly alleged that Bayer violated a condition of payment. *See* Bayer Mem. at 25.

discretion and made a determination that the uses at issue were not reasonable and necessary. Counts 7 and 8 therefore would fail under the Government's theory as well.

The Government also argues that "express 'false certification'" is not required where uses were not "reasonable and necessary." Statement at 4. Assuming for arguments' sake that the treatments at issue were not medically reasonable and necessary, the Government's position conflicts with controlling Third Circuit authority, which requires that claims under § 3729(a)(2) be supported by allegations of *express* false statements. *See Wilkins*, 659 F.3d at 306-07 (explaining that a claim under § 3729(a)(2) requires a "false record or statement," that is, that "a claimant for Government funds [make] an express false statement in order to obtain those funds"); Bayer Mem. at 25-26. However, this disagreement between Bayer and the Government is beside the point, because Simpson has not properly alleged that any claim was not legally reimbursable.

B. Simpson Has Not Properly Alleged That Any Claim Was "[T]ainted by" a Kickback Violation.

Under the Government's view, the payment of illegal kickbacks can lead to FCA liability for the claims that have been "tainted by those kickbacks." Statement at 5. But this position is of no help to Simpson because her kickback-based counts fail for multiple reasons not addressed by the Government.

First, the Statement expressly acknowledges that a relator cannot state an FCA claim based on kickback violations unless she properly alleges that the Anti-Kickback Statute ("AKS") was violated. Statement at 5, 7. As Bayer showed, however, Simpson's allegations of AKS violations are grossly deficient because they lack any allegations regarding critical facts such as fair market value for the physician services, commercial reasonableness, or actions (such as improper disclosure) that would cause otherwise permitted conduct to fall outside the statutory safe harbor for discounts (such as improper disclosure). *See* Bayer Mem. at 33 & n.25. The Government does not seek to defend Simpson on this front. Statement at 7.

Second, even if Simpson had properly alleged an AKS violation, she offers no factual allegations that any claim filed for reimbursement was "tainted by" the violation, *id.* at 5, only speculation that claims for payment must have somehow been the result of alleged kickbacks.[4] Under Third Circuit law, an AKS violation can provide the basis for FCA liability only if, *inter alia*, (1) the violation is made "in connection with a claim submitted to a federally funded insurance program," and (2) AKS compliance was certified as a condition of payment. *Wilkins*, 659

[4] Although the Government argues that Simpson's kickback counts should survive to the extent she has "properly alleged a violation of the AKS," Statement at 7, nothing in the Statement provides any support for the proposition that a relator can survive a motion to dismiss without alleging with particularity how the alleged AKS violation "tainted" a claim for payment.

F.3d at 306-07, 312. Simpson, however, has not alleged any nexus between the payment of kickbacks and the submission of claims. Nowhere in her complaint does she actually allege that any provider who received an illegal kickback also submitted a claim for payment; instead she simply asks this Court to *assume* that some unspecified claims were "the product" of kickbacks. Compl. at ¶ 385; *see id.* at ¶¶ 370, 377-78, 392-93. *See also* Bayer Mem. at 33-35. Simpson may believe that such claims were submitted, but a complaint that offers only a relator's speculation—without alleging any concrete facts to support the conclusion that a nexus exists—cannot survive under Federal Rules of Civil Procedure 8 and 9(b). *See, e.g., United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732-33 (1st Cir. 2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 677-78 (2009); Bayer Mem. at 32-35; Reply at 15-16.

Finally, the Government's suggestion that "a 'false certification' is not necessary to render a claim tainted by kickbacks false," Statement at 5, appears to be based on a recent statutory amendment that does not apply to this case. The Third Circuit has made clear that, although the AKS was amended in 2010 "to clarify that 'a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA],'" this amendment does not apply to conduct that took place prior to the date on which it was enacted, such as that which is the subject of Simpson's allegations. *See*

Wilkins, 659 F.3d at 311 n.19 (quoting 42 U.S.C. § 1320a–7b(g)). *See also* Bayer Mem. at 21 n.13 (complaint and briefs rely upon the statutes in effect at the time the alleged conduct occurred).

C. The Government's Position on Causation Is Inconsistent with Third Circuit Law.

Finally, with respect to both the misbranding and kickback counts, the Government actually rejects Simpson's argument that causation is not an element of an FCA claim. *Compare* Statement at 6-7, *with* Opp. at 31. Although the Government is correct that an FCA defendant "is responsible for the 'natural, ordinary, and reasonable consequences of his conduct,'" Statement at 6 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008)), the Third Circuit has held that—because doctors exercise independent medical judgment and because the federal drug laws do not "regulate the practice of medicine"—it is "pure conjecture" for a plaintiff to allege that a manufacturer's supposed marketing violations "caused the doctors to prescribe [a drug] for off-label uses." *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 248, 239-40 (3d Cir. 2012). Thus, in the Third Circuit, a plaintiff alleging fraudulent marketing to doctors must plead a nexus between the alleged fraud and *specific* prescriptions. *See id.*

The Government, citing a recent decision by the First Circuit from outside the FCA context, argues that a defendant might "reasonably foresee" that its

marketing practices could affect prescribing decisions, and a jury could make the "plausible inference" that the practices had that effect — without allegations or evidence that any actual doctor's decision was affected. Statement at 6-7 (citing *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 39 (1st Cir. 2013)). This causation analysis is inconsistent with the Third Circuit's decision in *Schering Plough*, which correctly holds that such reasoning is "pure conjecture" insufficient to show causation. 678 F.3d at 248.[5] Indeed, a complaint such as Simpson's, which offers no more than her own speculation that doctors may have been influenced, fails even the Rule 8 standard that a complaint must "permit the court to infer more than the mere possibility of misconduct." *Iqbal*, 556 U.S. at 679.

II. SIMPSON FAILS TO ALLEGE ANY MATERIALLY FALSE CLAIM UNDER THE APPLICABLE REIMBURSEMENT SYSTEMS.

The Government asserts that reimbursement under the Diagnosis Related Group ("DRG") system "does not necessarily preclude claims under the FCA" and that claims concealing information "material" to the government's payment decision can be false. Statement at 7-8 (capitalization altered). Bayer agrees and has not argued that a false claim could never result under the DRG system. As Bayer noted, courts have found DRG-related frauds actionable under the FCA

[5] It is also inconsistent with the First Circuit's own causation analysis in the FCA context, where it has recognized that courts cannot simply assume that doctors were influenced by a marketing scheme. *See Rost*, 507 F.3d at 732-33.

where the alleged fraud was material to payment (such as frauds involving the miscoding of patients into improper DRGs or the inclusion of unallowable charges). *See* Reply at 22 & n.14 (citing cases).

If, however, the allegedly false information would *not* have been material to the government's payment decision, the FCA claim may not proceed as a matter of law. *See* Bayer Mem. at 26-27, 29-30; Reply at 19-20, 22-23 (both citing cases). Here, Simpson has not adequately alleged, and cannot allege, materiality for her drug misbranding counts given that (a) claims are submitted for an entire hospital stay for a pre-set amount based on the patient's clinical information and (b) the government's payment decision generally does not depend on what drugs—if any—were used in the course of treatment. *See* Bayer Mem. at 26-30; Reply at 19-23. The Government does not suggest that an alleged marketing violation would be material where, as here, the Government would pay the same amount for a patient's care regardless of whether the patient received Trasylol.

III. SIMPSON HAS NOT ALLEGED SUFFICIENT BILLING DETAILS UNDER ANY ACCEPTED PLEADING STANDARD.

As Bayer has explained, the submission of a claim is an essential element of the fraudulent scheme in an FCA case, and that element must be pled with particularity under Rule 9(b) by alleging representative examples. *See* Bayer Mem. at 34-35 (citing cases); Reply at 12-13 (same). The Government nevertheless urges this Court to accept the view that "the allegation of a specific

false claim is not an absolute prerequisite to pleading a viable FCA claim." Statement at 8. That is not the law in the Third Circuit. Even so, Simpson's FCA counts would fail under the cases cited by the Government.

The Government invokes decisions by several other courts of appeals, holding that a relator need not produce the claims themselves if she alleges sufficient other details about the billing process to ensure she is not proceeding based on speculation. *See, e.g.*, *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 192 (5th Cir. 2009); Statement at 8. However, the complaints that survived in these cases alleged a high level of detail regarding how claims were submitted and what they contained.[6] Thus, even under the precedents cited by the Government, the complaints included sufficient detail to provide a "means of injecting precision and … substantiation" regarding the alleged false claims and

[6] *See Grubbs*, 565 F.3d at 192 (relator alleged "specific dates … and often the type of … code that would have been used in the bill"); *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) (complaint "name[d] specific parts shipped on specific dates, and … relate[d] details of payment"); *see also Rost*, 507 F.3d at 733 (relator who alleged a detailed fraud involving off-label marketing failed to satisfy Rule 9(b) where the submission of claims was "possible" but nonetheless speculative). To the extent that the district court in *United States ex rel. Singh v. Bradford Regional Medical Center*, No. 04-186 ERIE, 2006 WL 2642518 (W.D. Pa. Sept. 13, 2006), held that Rule 9(b) was satisfied based on speculation that claims might have been submitted, that decision was incorrect. *See* Reply at 13 & n.7. Even in that case, however, the relator was able to provide some level of substantiation by identifying specific providers involved in the submission of claims. *Id.* at *1. Simpson has failed to do even this.

thereby avoided grounding those cases on speculation. *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984).

The Government's assertion that "nothing is gained by requiring the relator to identify specific claims individually," Statement at 9, ignores the fundamental requirement that an FCA claim may not proceed on speculation that false claims must have been submitted. *See, e.g., Rost*, 507 F.3d at 733 (explaining that courts should not speculate, without particularized allegations, that a given set of providers submitted claims to the government); *see also Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013) (relator must identify specific false claims if the defendant's alleged conduct "*could* have led, but *need not necessarily* have led, to the submission of false claims"). The Government's assertion should, then, be rejected by this Court and, once it is, Simpson's complaint necessarily fails. *See* Bayer Mem. at 31-35; Reply at 12-16.

CONCLUSION

For the foregoing reasons, and those stated in Bayer's briefs, Simpson's Seventh Amended Complaint should be dismissed with prejudice.

Respectfully submitted,

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